

REMARKS

Applicant respectfully requests reconsideration of the application in view of the following remarks.

Claims 103-119 were pending in the application. Applicant has amended claims 111 and 112 to provide an antecedent basis for the claim term “undulating elements.” No other claim amendments have been made. Therefore, claims 103-119 are still pending in the application.

OATH/DECLARATION

The Examiner correctly notes that the oath/declaration is defective because it refers to a non-related application, i.e., 08/358350. This is a typographical error. The correct number of the related application is 09/358350. A new oath/declaration identifying the correct related application will be submitted in a subsequent paper.

SPECIFICATION

Applicant thanks the Examiner for pointing out the incorrectly numbered subsections in Section A. Applicant has amended the specification to correct this problem. The subsection following subsection (ii) is now numbered (iii), and so on.

CLAIM REJECTION UNDER 35 U.S.C. § 112

The Examiner rejected claims 111 and 112 under 35 U.S.C. § 112, second paragraph as being indefinite because there is no antecedent basis for the claim term “the undulating elements.” Applicant thanks the Examiner for correctly noting that claims 111 and 112 should depend from claim 109 to avoid the antecedent basis problem. Applicant has amended claims 111 and 112 in accordance with the Examiner’s suggestion and now requests withdrawal of the rejection.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103

Myers et al (USPN 5,700,285) in view of Choi et al (USPN 4,131,648)

The Examiner rejected claims 103-105, 107, and 113-117 under 35 U.S.C. § 103 as being allegedly unpatentable over Myers in view of Choi.

Applicant respectfully submits that Myers in combination with Choi does not render the pending claims obvious to one of ordinary skill in the art. The U.S. Court of Appeals for the Federal Circuit has held that “[t]he PTO has the burden under section 103 to establish a *prima facie* case of obviousness...It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.” In re Fine, 837 F.2d 1071, 1074 (Fed. Cir. 1988).

Applicant respectfully submits that there is no basis which would support the combination of Myers and Choi to make the pending claims obvious. The Examiner is correct in asserting that Choi teaches an erodible coating that comprises a therapeutic agent. However, the Examiner’s assertion that Choi teaches an implantable device coated with an erodible polymer is incorrect. Choi teaches that the erodible polymers disclosed in Choi “can be made into” implantable devices (see Choi, col. 28, ll. 15-17) but that is very different from coating an implantable device such as a stent-graft with a drug-containing polymer. Thus, Choi offers no teaching of coating an implantable device with the erodible polymers that it discloses.

Needless to say, Choi offers no suggestion whatsoever that a stent-graft can be coated with the polymers disclosed in Choi. In fact, Choi does not once mention either the term “stent” or the term “graft.” Therefore, Choi provides no motivation that would lead one of ordinary skill in the art to combine Choi with Myers to make the claimed invention obvious.

“The examiner bears the burden of establishing a *prima facie* case of obviousness.” ; In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Only if the burden of establishing a *prima facie* case of obviousness is met by the Examiner, does the burden of coming forward with rebuttal argument or evidence shift to the applicant. In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). When the references

cited by the examiner fail to establish a *prima facie* case of obviousness, the rejection is improper and will be overturned. Fine, 837 F.2d at 1074, 5 USPQ2d at 1598 (Fed. Cir. 1988). In re Deuel, 51 F.3d 1552, ___, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995).

Combinations of known elements are patentable. Even if the Examiner had cited references containing all the elements of the claims, that would not preclude patentability. A new combination of elements can be patented “whether it be composed of elements all new, partly new or all old.” Rosmount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1546, 221 USPQ 1, 7 (CAFC 1984). In fact:

Most patentable inventions combine old elements. **The fact that a patent combines teachings from prior art references is irrelevant to the legal determination of obviousness under § 103** and the factual inquiries set forth in *Graham* “The critical inquiry is whether ‘there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.’” Fromson v. Advance Offset Plate, Inc., 755 F.2d 1549, 1556 [225 USPQ 26, 31] (Fed. Cir. 1985) (citation omitted) (emphasis in original) Intra Corporation v. Hamar Laser, 662 F. Supp. 1420, 1440-1441, 4 USPQ2d 1337, 1352, 1353 (E.D. Mich. 1987), citations omitted, emphasis added; aff’d, 862 F.2d 320 (CAFC 1988)(unpublished).

***Prima facie* obviousness requires a specific motivation to combine references.**

“To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).” MPEP 2142.

No specific motivation to make the claimed combination has been provided.

Case law requires that the Examiner provide a specific motivation in the art for combining known elements in order to establish obviousness of the combination.

“[C]ase law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. ... Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the

inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. ... [Evidence of a suggestion, teaching, or motivation to combine] must be clear and particular. ... Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.' ... [A] reference-by-reference, limitation-by-limitation analysis fails to demonstrate how the [cited] references teach or suggest their combination ... to yield the claimed invention," and a conclusion of obviousness based on such an analysis "as a matter of law, cannot stand." In re Dembiczak, 175 F.3d 994, 999, 1000, 50 USPQ2d 1614, 1617, 1618 (Fed. Cir. 1999).

No clear, particular suggestion or motivation in the prior art to make the specific combination of a stent, a polymer-therapeutic substance coating on the stent and a PTFE tape wrapped on the outside of the stent as recited in the pending claims has been provided. In the absence of a specific suggestion in the prior art, a rejection identifying individual elements of the claimed combinations is based merely on hindsight in light of Applicant's disclosure. *Prima facie* obviousness has not been established under such conditions, and a rejection based on such an unmotivated combination of references will not stand as a matter of law.

As the cited references do not teach all the elements of the pending claims, and no specific motivation in the prior art to modify and combine the references has been provided, *prima facie* obviousness has not been established. The Examiner is respectfully requested to withdraw this rejection.

Other Claim Rejections Under 35 U.S.C. § 103

The Examiner rejected various other claims under § 103 by combining Myers and Choi with various other references. As the foregoing shows, the Examiner has not established a *prima facie* case for combining Myers with Choi to render the pending claims obvious. Therefore, the Examiner has not established a *prima facie* case for combining Myers with Choi and then further with a third reference. Furthermore, the claim rejections herein are only of claims dependent on claim 103. Because Applicant has shown above that claim 103 is patentable over Myers in view of Choi, all the claims dependent on claim 103 are also patentable.

Applicant respectfully submits that, for all of the foregoing reasons, rejection of the pending claims under 35 U.S.C. § 103 is not supported by law and, therefore, should be withdrawn.